

**NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Treatment for Movement Disorders**

**Medicaid and Health Choice
Effective Date: February 8, 2018
Amended Date: November 21, 2018**

Therapeutic Class Code: H6L

Therapeutic Class Description: Drugs to Treat Movement Disorders

Medication	Generic Code Number(s)	NDC Number(s)
Ingrezza	43266	
Austedo	43228, 43236, 43237	
Xenazine	15508, 49900	
tetrabenazine	15508, 49900	

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- that is unsafe, ineffective, or experimental/investigational.
- that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to

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correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at <http://www.ncdhhs.gov/dma/epsdt/>. coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

1. Ingrezza

a. Tardive Dyskinesia

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of moderate to severe Tardive Dyskinesia.
- Beneficiary is age 18 or older.
- Provider has submitted documented baseline evaluations of the condition using either:
 - Abnormal Involuntary Movement Scale (AIMS)
 - Extrapyramidal Symptom Rating Scale (ESRS)
- Beneficiary has had a previous trial of an alternative method to manage the condition.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

2. Austedo

a. Tardive Dyskinesia

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of moderate to severe Tardive Dyskinesia.
- Beneficiary is age 18 or older.
- Provider has submitted documented baseline evaluations of the condition using either:
 - Abnormal Involuntary Movement Scale (AIMS)
 - Extrapyramidal Symptom Rating Scale (ESRS)
- Beneficiary has had a previous trial of an alternative method to manage the condition.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.

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- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

b. Huntington's Disease

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of Huntington's Disease and is experiencing signs and symptoms of chorea
- Beneficiary is age 18 or older.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.
- Initial approval shall be for up to 6 months.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

3. Xenazine and tetrabenazine

a. Huntington's Disease

Criteria for Initial Coverage:

- Beneficiary has a diagnosis of Huntington's Disease and is experiencing signs and symptoms of chorea
- Beneficiary is age 18 or older.
- Beneficiary is not receiving dual therapy with other vesicular monoamine transporter 2 (VMAT2) inhibitors.
- Beneficiary is not concurrently using a MAOI (monoamine oxidase inhibitor) or reserpine.

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- Initial approval shall be for up to 6 months.
- Beneficiaries with a history of depression or suicidal ideation are being treated and/or are stable.

Criteria for Continuation of Coverage:

- All of the above criteria are met.
- Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
- Reauthorization shall be for up to 12 months.

References

1. Prescriber Information—Ingrezza®. Neurocrine Biosciences, Inc., San Diego, CA. April 2017.
2. Prescriber Information—Xenazine®. Lundbeck, Deerfield, IL. revised September 2017.
3. Prescriber Information—Austedo®. Teva Pharmaceuticals, USA, Inc., North Wales, PA. revised August 2017.

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Criteria Change Log	
02/08/2018	Criteria effective date
11/21/2018	Added criteria for Austedo, Xenazine, and tetrabenazine